

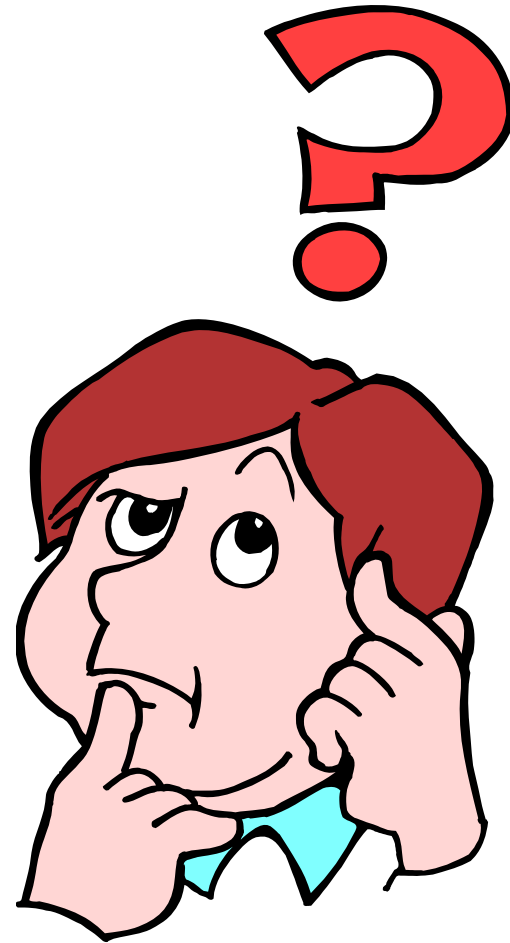
Content of Labeling - SPL Format

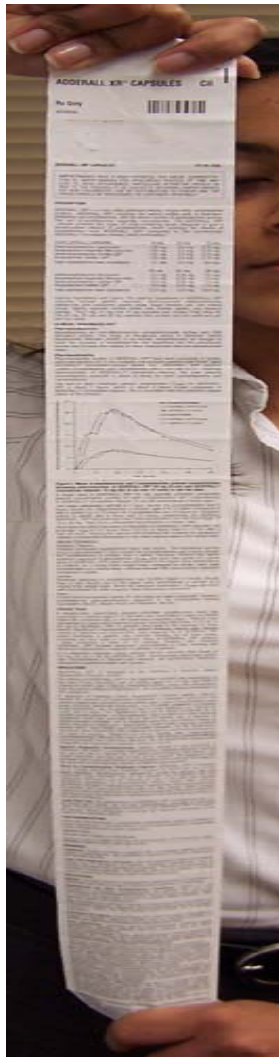
SPL Release Four Training Session – Module 4

Lonnie Smith
Project Manager
FDA Data Standards Council

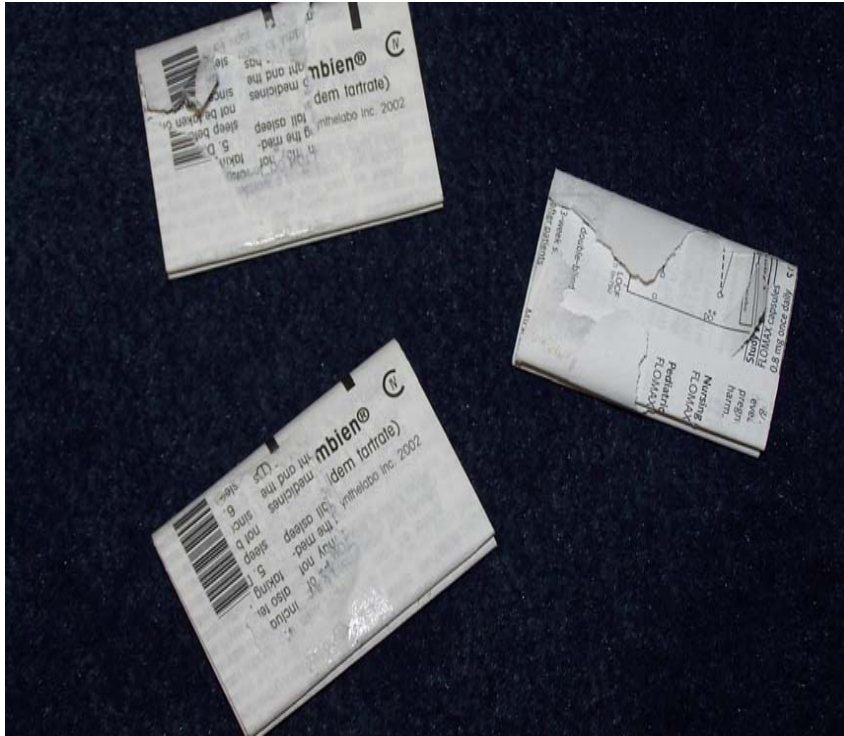


- WHY CHANGE
THE **CONTENT OF**
LABELING THAT
HAS WORKED FOR
DECADES ????





- Difficult to read - Font size and paper shape limits readability and duplication
- Difficult to access – distribution limited (e.g., pharmacy shelf)
- Difficult to use – information in paper labels cannot be accessed by computer systems



- The Labeling Rips when it is Removed!
- Critical data is missing.
- The Product can outdate the Labeling
- The Labeling is Often in the Container

20 mg), bottles of 100, NDC 54092-387-01

ADDERALL XR® 25 mg Capsules: Orange/white (imprinted ADDERALL XR 25 mg), bottles of 100, NDC 54092-389-01

ADDERALL XR® 30 mg Capsules: Natural/orange (imprinted ADDERALL XR 30 mg), bottles of 100, NDC 54092-391-01

Dispense in a tight, light-resistant container as defined in the USP.

Store at 25° C (77° F). Excursions permitted to 15-30° C (59-86° F) [see USP Controlled Room Temperature]

ANIMAL TOXICOLOGY

Acute administration of high doses of amphetamine (d- or d,l-) has been shown to produce long-lasting neurotoxic effects, including irreversible nerve fiber damage, in rodents. The significance of these findings to humans is unknown.

Manufactured by DSM Pharmaceuticals Inc., Greenville, North Carolina 27834. Distributed and marketed by Shire US Inc., Newport, KY 41071

For more information call 1-800-828-2088 or visit www.adderallxr.com

ADDERALL® is registered in the US Patent and Trademark Office

403958

381 0107 001

(rev. 10/2002)

Shire

Labeling Sections are Difficult to Locate

The amount of intervening text **varies.**

Section locations occasionally **vary.**

This variability results in **wasted time and effort** looking for the critically needed drug information!

Components of SPL

- Administrative
- Content of Labeling
- Product data elements

SPL Stylesheet View/Source Code

CONTRAINDICATIONS

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from
any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```

Administrative (Document Tracking Information)

Basic information to identify the SPL document:

- **Document ID:** is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case.
- **Document Type:** The `<code>` is the LOINC code which provides information on the document type.
- **Effective Time:** provides a date reference to the SPL version including the year, month and day as yyyyymmdd.
- **SetID:** is a GUID and is a unique identifier for the document that remains constant through all versions/revisions of the document.
- **Version number:** is an integer greater than zero that provides a sequence to the versions of the document.

Content of Labeling

- Sections and Subsections
- Symbols and Characters
- Font Effects
- Footnotes
- Lists
- Tables
- Images

CoL & eList Data

- Content of labeling and product data elements are included in ONE document
- Keeps content of labeling and data elements for listing in one document

Fulfill Two Regulatory Requirements

- Companies with application products regulated by CBER & CDER can fulfill two regulatory requirements using SPL
 - Electronic Labeling Rule – Prescription drug products
 - Drug listing (electronically)

Drug Listing/CoL SPL Document

MIRACLE XR - good drug tablet
Acme Pharmaceuticals, Inc

Miracle XR

Description

Description text placeholder

Additional Info in CoL SPL R4 File

- Attached information
- Product Data Elements
- Establishment Info
- Registrant Info

Transitioning from SPL R3 to R4

- R4 SPL with highlights R4 documents:
 - Ensure that you enter title for release four SPL (drug names, Initial US approval date, etc...)
 - Boilerplate text for “title” is no longer rendered by stylesheet.
 - Include adverse reactions statement as free text
 - boilerplate text for this section no longer rendered by stylesheet in **SPL R4**
 - (boilerplate text still rendered for SPL R3 PLR documents)

SPL Document Titles (R3 & R4)

- SPL document “titles” – Rendering of title information altered in response to Applicant/Reviewer feedback
- SPL Release Three documents – “SPL Header/Title” – concatenation of data elements
- SPL Release Four documents – “title” – free text entered by document authors

SPL R3 Header/SPL Title

- Final SPL

ADREVIEW - iobenguane i 123 injection
GE Healthcare



SPL R3 Header

Generated by data elements

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ADREVIEW safely and effectively. See full prescribing information for ADREVIEW.

ADREVIEW (iobenguane i 123) injection for intravenous use
Initial U.S. Approval: 2008



SPL R3 "Title"

Generated by data elements

SPL R3 Header/Title cont...

- Approved PI (PDF)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AdreView safely and effectively. See full prescribing information for AdreView.

AdreView (Iobenguane I 123 Injection) for Intravenous Use
Initial U.S. Approval: 2008

SPL R4 Header/Title

- Final SPL

ADREVIEW - iobenguane i 123 injection
GE Healthcare

SPL R4 Header
Generated by data elements



HIGHLIGHTS OF PRESCRIBING INFORMATION

AdreView (Iobenguane I 123 Injection) for Intravenous Use
Initial U.S. Approval: 2008

SPL R4 Title
Generated by free text



SPL R4 Header/Title cont...

- Approved PI (PDF)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AdreView safely and effectively. See full prescribing information for AdreView.

AdreView (Iobenguane I 123 Injection) for Intravenous Use
Initial U.S. Approval: 2008

SPL R4

Adverse Reactions Statement

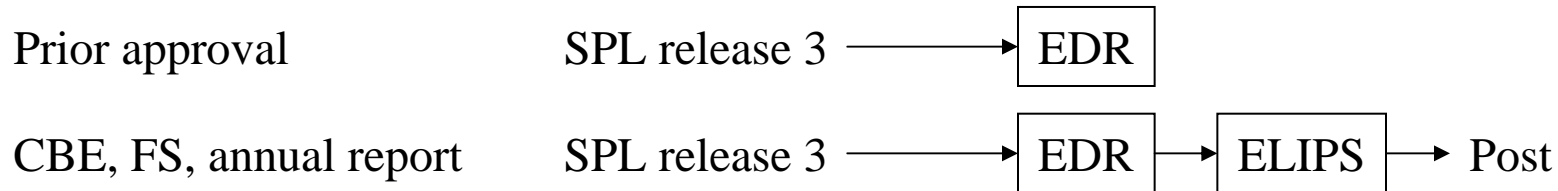
- SPL R3 – Boilerplate text
- SPL R4 – Free text – as entered by document author
- (looks similar in both releases)

SPL Submission for Application Product Listing in Paper Format

Under Consideration

Submission	Applicant	FDA	Public
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Application

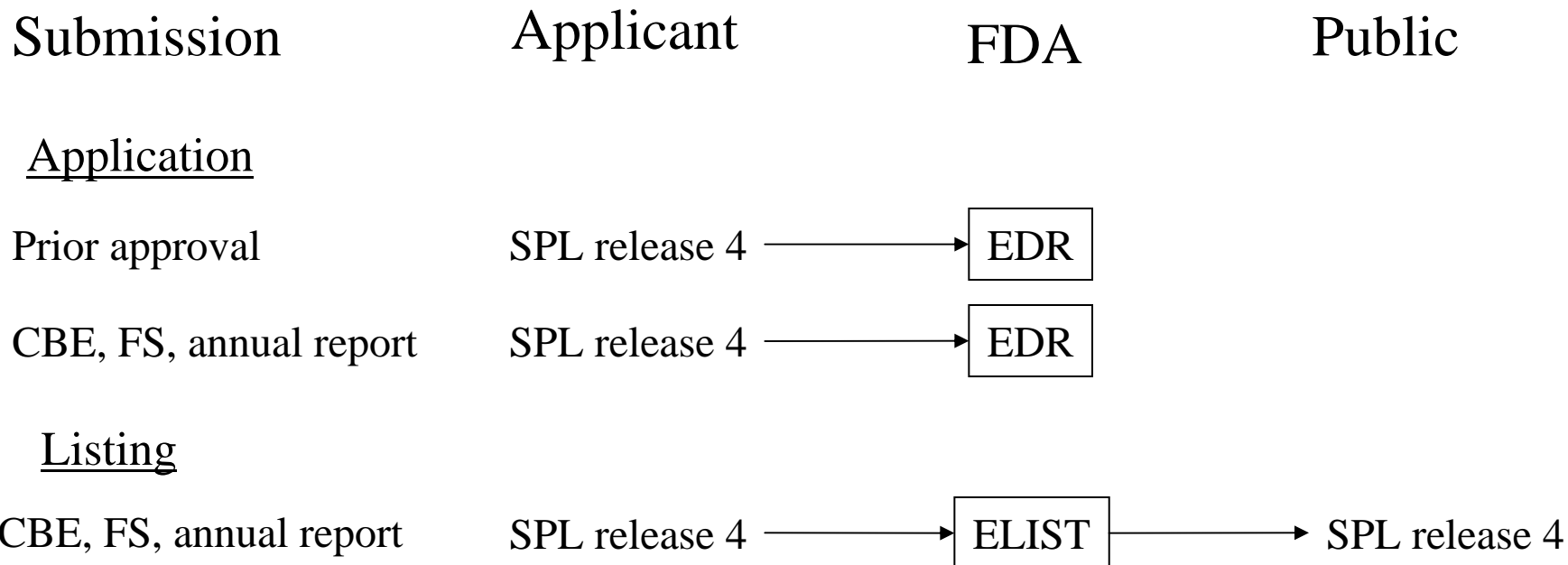


Listing

CBE, FS, annual report	Paper
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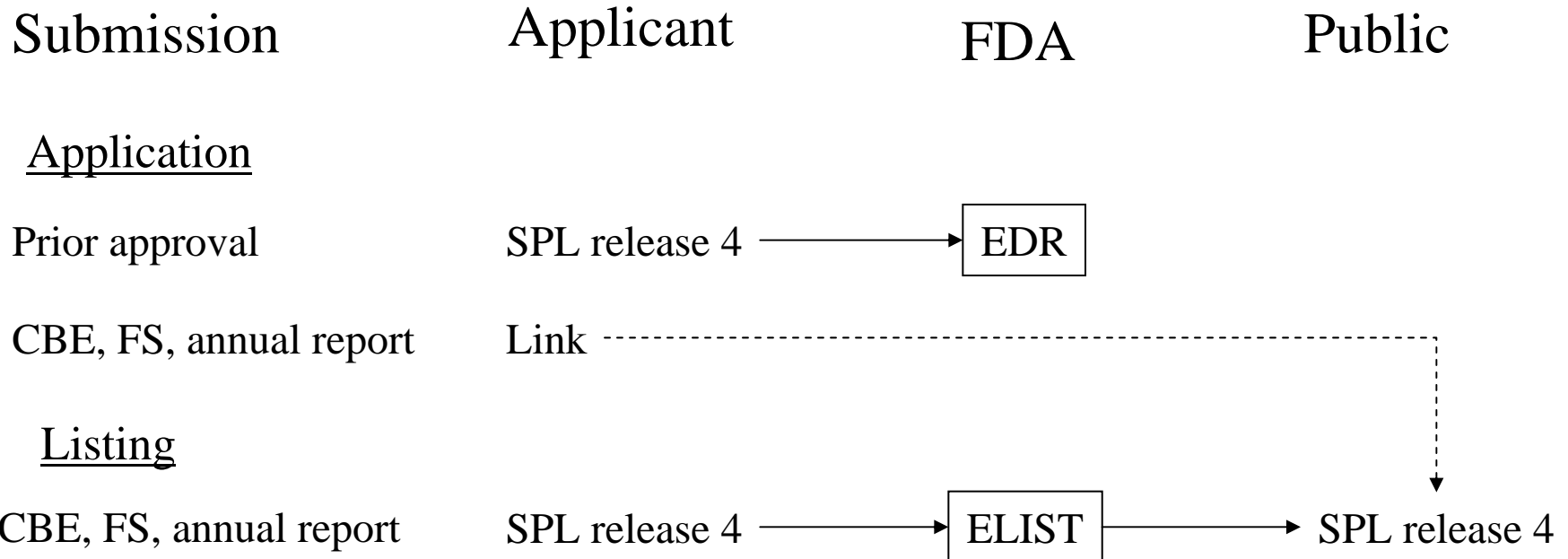
SPL Submission for Application Product Listing in Electronic Format

Under Consideration



Product Listing in Electronic Format with Link to Posted SPL file

Under Consideration



SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)

Next Session

- Product Data Elements